APPENDIX

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 79-1104

AMERICAN PETROLEUM INSTITUTE, PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR, and ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

AMERICAN PETROLEUM INSTITUTE AND 15 OF ITS MEMBER COMPANIES, CHEMICAL MANUFACTURERS ASSOCIATION, THE ST. LOUIS REGIONAL COMMERCE & GROWTH ASSOCIATION, NATURAL RESOURCES DEFENSE COUNCIL, ET AL., THE STATE OF OKLAHOMA, E. I. DU PONT DE NEMOURS & CO., INTERVENORS

No. 79-1201

E. I. DU PONT DE NEMOURS AND COMPANY, PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR, and ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 79-1222

AMERICAN PETROLEUM INSTITUTE, ET AL., PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY, and DOUGLAS M. COSTLE, ADMINISTRATOR

No. 79-1290

CHEMICAL MANUFACTURERS ASSOCIATION, PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR, and
ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 79-1335

THE NATURAL RESOURCES DEFENSE COUNCIL, INC., ET AL., PETITIONERS

v.

DOUGLAS M. COSTLE, ADMINISTRATOR OF THE
ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 79-1359

CHEMICAL MANUFACTURERS ASSOCIATION, PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR, and
ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 79-1362

THE CONNECTICUT LUNG ASSOCIATION, INC., PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR OF THE
U.S. ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 79-1356

SIERRA CLUB, PETITIONER

v.

DOUGLAS M. COSTLE, ADMINISTRATOR OF THE
ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT

No. 79-1365

COMMONWEALTH OF VIRGINIA, *ex rel.*
THE STATE AIR POLLUTION CONTROL BOARD, PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY and
DOUGLAS M. COSTLE, ADMINISTRATOR, RESPONDENT

No. 79-1367

CITY OF HOUSTON, TEXAS, PETITIONER

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGECY
and DOUGLAS M. COSTLE, ADMINISTRATOR, RESPONDENT

Petitions for Review of Orders of the
Environmental Protection Agency

Argued February 26, 1980

Decided September 3, 1981

Edward W. Warren with whom *Robert F. Van Voorhees, John S. Hahn, Stark Ritchie* and *David T. Deal* were on the brief, for American Petroleum Institute petitioner in Nos. 79-1104 and 79-1222 and intervenor in Nos. 79-1335, 79-1356 and 79-1362.

Roger L. Chaffe, Assistant Attorney General, for Commonwealth of Virginia, etc., petitioner in No. 79-1365. *Frederick S. Fisher* and *James E. Ryan, Jr.*, also entered appearances for Commonwealth of Virginia, etc., petitioner in No. 79-1365.

Courtenay Ellis with whom *David A. Donohoe* was on the brief, for City of Houston, Texas, petitioner in No.

79-1367. *Daniel Joseph* also entered an appearance for City of Houston, Texas, petitioner in No. 79-1367.

Richard Ayres with whom *David D. Doniger* was on the brief, for Natural Resources Defense Council, Inc., et al., petitioner in Nos. 79-1335, and 79-1362 and intervenor in No. 79-1104.

John H. Pickering, Andrew T. A. MacDonald and *Edmund B. Frost* were on the brief, for Chemical Manufacturers Association petitioner in Nos. 79-1290 and 79-1359 and Intervenor in Nos. 79-1104, 79-1335, 79-1356 and 79-1362. *David R. Johnson* and *John Stephen Lawrence, Jr.*, also entered appearances for Chemical Manufacturers Association, petitioner in Nos. 79-1290 and 79-1359 and intervenors in Nos. 79-1335, 79-1356 and 79-1362.

Joseph J. Brecher was on the brief, for Sierra Club, Petitioner in No. 79-1356. *Peter J. Herzberg* also entered an appearance for Sierra Club, petitioner in No. 79-1356.

Patrick K. O'Hare, Attorney, Environmental Protection Agency and *Patrick J. Cafferty, Jr.*, Attorney, Department of Justice with whom *Angus Macbeth*, Acting Assistant Attorney General, *Donald W. Stever*, Attorney, Department of Justice and *Gerald K. Gleason*, Deputy Associate General Counsel, Environmental Protection Agency were on the brief, for respondents. *Jeffrey O. Cerar*, Attorney, Environmental Protection Agency also entered an appearance for respondent, Environmental Protection Agency.

Christopher S. Bond and *Charles A. Blackman* were on the brief, for the St. Louis Regional Commerce and Growth Association, intervenor in Nos. 79-1104, 79-1335, 79-1356 and 79-1362.

Charles S. Rogers, Assistant Attorney General, State of Oklahoma also entered an appearance for State of Oklahoma, etc., intervenor in No. 79-1104.

Robert R. Bonczek, Carl B. Everett, and *Bernard J. Reilly* also entered appearances for E.I. DuPont De Nemours and Company petitioner in No. 79-1201 and intervenor in Nos. 79-1104, 79-1335, 79-1356 and 79-1362.

Before: ROBB, WALD and MIVKA, *Circuit Judges.*

Opinion for the Court filed by *Circuit Judge* ROBB.

Opinion dissenting in part filed by *Circuit Judge* WALD.

ROBB, *Circuit Judge*: The petitions for review consolidated in this case challenge the primary and secondary national ambient air quality standards[1] for ozone promulgated by the Environmental Protection Agency (EPA) under the Clean Air Act, as amended. 42 U.S.C. §§ 7401, et seq. (Supp. III 1979). EPA established both the primary and secondary standards for ozone at 0.12 parts per million (ppm) in final regulations published on February 8, 1979. 44 Fed. Reg. 8202. Petitioners American Petroleum Institute (API), *et al.*, the City of Houston, and the Commonwealth of Virginia contend that the Administrator of EPA erred by establishing too stringent standards. Petitioner National Resources Defense Council (NRDC), et al., argues that the Administrator erred by establishing standards that are too lenient. Various petitioners raise procedural challenges, and certain petitioners challenge regulations which implement the standards. We uphold the ozone standards because they are proper under the Act and such procedural errors as did occur do not require invalidation of the final standards.

I.

The standards challenged in this case establish restrictions on permissible levels of ozone. As with other photochemical oxidants, ozone is not emitted directly into the air, but is produced by complex chemical reactions

[1] These regulations are codified at 40 C.F.R. § 50.9(a) (1980).

between organic compounds (precursors) and nitrogen oxides in the presence of sunlight. Oxidant precursors are organic compounds which can occur naturally but are in large measure man-made. Sources of precursors include automobile emissions of hydrocarbons, chemical plant emissions, and gasoline vapors. Photochemical oxidant concentrations can also exist where ozone from the stratosphere intrudes into the lower atmosphere or where naturally occurring nitrogen oxides react with hydrocarbons produced by vegetation. Although ozone is but one of many photochemical oxidants, total oxidant pollution has been measured by reference to the ozone level in the air since 1971.

Ozone is the primary cause of the ill effects associated with smog, of which it usually comprises 65-100%. At certain concentration levels, ozone irritates the respiratory system and causes coughing, wheezing, chest tightness, and headaches. Due to its irritating nature, ozone can aggravate asthma, bronchitis, and emphysema. Some studies indicate that chronic exposure to fairly low levels of ozone may reduce resistance to infection and alter blood chemistry or chromosone structure. Ozone can destroy vegetation, reduce crop yield, and damage exposed materials by causing cracking, fading, and weathering.

The goal of the Clean Air Act is to protect the public health and welfare by improving the quality of the nation's air. 42 U.S.C. § 7401(b). Improved air quality is accomplished by the establishment of national ambient air quality standards (NAAQS) and by implementation thereof through state programs to control local sources of pollution. 42 U.S.C. § 7410. The Act directs the Administrator to establish two types of NAAQS. Primary ambient air quality standards are "standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." 42 U.S.C. § 7409(b)(1).

Secondary standards "specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air." 42 U.S.C. § 7409 (b) (2). State control programs must provide for the attainment of primary standards "as expeditiously as practicable but . . . in no case later than three years from the date of aproval of such plan . . ." 42 U.S.C. § 7410 (a) (2) (A) (i). State programs that implement secondary standards must specify a "reasonable time at which such secondary standard will be attained". 42 U.S.C. § 7410 (a) (2) (A) (ii). Thus, the ozone standards at issue in this case must be implemented through state plans within three years for the primary standard and within a reasonable time for the secondary standards.[2] *Lead Industries Ass'n v. EPA*, No. 78-2201 (D.C. Cir. June 27, 1980) slip op. at 7-8, cert. denied, 49 U.S.L.W. 3428 (Dec. 8, 1980).

EPA promulgated primary and secondary standards for photochemical oxidants (i.e., ozone) in 1971. Both standards were established at an 0.08 ppm hourly average not to be exceeded more than once a year. 36 Fed. Reg. 8187 (1971). The method used to determine compliance with the 1971 standards measured only ozone. 43 Fed. Reg. 26967 (1978). In 1976 EPA began to revise the 1971 standards and in April 1977 requested data and information relevant to the revision. 42 Fed. Reg. 20493 (1977).

As part of the revision, EPA established a working group within the Criteria and Special Studies Office of its Office of Research and Development to develop a

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[2] Under 42 U.S.C. § 7501 (a) (2) a state that cannot meet the NAAQS for ozone by December 31, 1982 despite the implementation of "all reasonably available measures" may seek approval of a plan that extends the deadline for compliance to December 31, 1987.

"criteria document". A criteria document "accurately reflect[s] the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." 42 U.S.C. § 7408(a)(2); *see* 42 U.S.C. § 7409(a). In the early stages of preparing the ozone criteria document EPA retained a panel of expert environmental consultants (the Shy Panel) and sought their opinions on the ozone concentration levels at which adverse health effects might be experienced. The Shy Panel concluded that "short term exposures to ozone in the range of 0.15 to 0.25 ppm may impair mechanical function of the lung, and may induce respiratory and related symptoms in sensitive segments of the population". (J.A. 270) The panel recommended that the primary standard remain at 0.08 ppm. (J.A. 277) The panel's recommendations and conclusions were included in the draft criteria document.

In 1974 the Administrator of the EPA established a Science Advisory Board (SAB) to assist in establishing NAAQS, among other functions. During the revision of the ozone standards Congress passed the Environmental Research, Development, and Demonstration Authorization Act of 1978, PUB.L. 95-155, 91 Stat. 1260 (1978) (ERDDAA), which requires the Administrator to submit to the SAB any "proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the [EPA] . . . on which the proposed action is based." 42 U.S.C. § 4365(e). During the revision of the ozone standard the SAB reviewed two full drafts and a third draft of the summary chapter of the ozone criteria document and offered comments on its content. After examining the summary of the third draft, six of the eleven SAB members voted to approve the criteria document, with reservations and recommended changes. Two members rejected the document, and three members offered no judgment. The parties dispute the

effect of this "approval" under the Clean Air Act. Neither the final criteria document nor the final ozone standards were made available to the SAB for comment.

As a further aid to the Administrator in establishing the ozone standards, EPA conducted a "risk assessment study". This study combined medical opinions as to the necessary ozone levels for creation of certain adverse health effects (e.g., aggravation of emphysema) with predictions as to peak ozone levels in a five-year period. (J.A. 561-73) The study attempted to predict the probability of creating certain health problems under various possible standards. The Shy Panel relied on the results of this study in recommending that the primary standard remain at 0.08 ppm. Although the risk assessment study results were summarized in the preamble to the final regulations, 44 Fed. Reg. 8216 (1979), the Administrator acknowledged that the method used in arriving at the results was not completely reliable. 44 Fed. Reg. 8210-11 (1979). The parties dispute whether the results of the risk assessment study played a significant role in the establishment of the ozone standards.

On June 22, 1978 EPA published the proposed primary and secondary standards for ozone. 43 Fed. Reg. 26962. The proposed primary standard was raised to 0.10 ppm, while the proposed secondary standard remained at 0.08 ppm. EPA also proposed a revision in the measuring standard (the one-exceedance-per-year attainment measure) by substitution of a new standard. Under the old standard, as long as the 0.08 ppm standard was not exceeded more than once a year, the standard was met. The new measuring standard is met when "the expected number of hour[s] per calendar year with concentrations above 0.10 ppm is less than or equal to one [over a three year period]". 43 Fed. Reg. 26968 (1978). In setting the proposed primary standard at 0.10 ppm the Administrator relied on studies showing adverse health effects at ozone concentrations of 0.15 to 0.35 ppm. 43

Fed. Reg. 26966 (1978). He also relied on medical opinions and some of the conclusions of the risk assessment study. *Id.* at 26966-67. The proposed secondary standard was based on predictions as to the effects of certain ozone concentrations on crop yields due to leaf damage. 43 Fed. Reg. 26969 (1978).

After publication of the proposed standards, EPA conducted four public hearings on the standards and received numerous comments. Various governmental agencies commented on the proposed standards, including the Departments of Interior, Energy, and Transportation, the United States Public Health Service, the Virginia Air Pollution Control Board, and various White House officials. 44 Fed. Reg. 8206-07 (1979). Some of these comments occurred after the official comment period closed and are the subject of dispute in this case.

In February 1979 EPA published final primary and secondary standards for ozone, raising both to 0.12 ppm. 44 Fed. Reg. 8202. The Administrator determined that "the most probable level for adverse health effects in sensitive persons, as well as in healthier (less sensitive) persons who are exercising vigorously, falls in the range of 0.15 to 0.25 ppm." 44 Fed. Reg. 8216 (1979). He based his conclusion on the criteria document, the comments submitted on the proposed standards, the report of the Shy Panel, and medical opinions collected during the risk assessment study. 44 Fed. Reg. 8215-16 (1979). The Administrator also concluded that the 0.12 ppm standard provides an adequate margin of safety. 44 Fed. Reg. 8216-17 (1979). He raised the proposed secondary standard based on a determination that average daily maximum ozone concentrations of 0.12 ppm would not harm crop yields. 44 Fed. Reg. 8217-18 (1979). Finally, in addition to establishing ozone standards, EPA published four models for determining the amount of hydrocarbon reduction necessary to meet the standards. 44 Fed. Reg. 8234 (1979). No petitions for reconsideration

of the standards were filed with EPA. Petitions for review pursuant to 42 U.S.C. § 7607(b)(1) followed.

II.

Issues Presented By The Petitions

The petitions for review present both substantive and procedural challenges to the primary and secondary ozone standards promulgated by EPA. Some petitioners contend that the standards are irrational and unsupported by the record. Other petitioners argue that the standards do not contain an adequate margin of safety, are too stringent given naturally occurring ozone levels, and are not economically feasible. It is also argued that the measurement standards and control strategies promulgated by EPA are unreasonable and unsupported by the record. As to the procedural allegations, it is argued that the Administrator erred in his use of the Science Advisory Board, the Shy Panel, and the risk assessment study. Various petitioners contend that certain items excluded from the record should have been included, while other petitioners argue that some material was untimely inserted in the record. After discussing the standard of review which governs petitions for review under the Clean Air Act, we address each significant argument in turn.

III.

Standard Of Review

Section 307 of the Clean Air Act provides, in relevant part:

* * * *

> (b)(1) A petition for review of action of the Administrator in promulgating any national primary or secondary ambient air quailty standard . . . may be filed only in the United States Court of Appeals for the District of Columbia.

* * * *

(d) (1) This subsection applies to —

(A) the promulgation or revision of any national ambient air quality standard under section 7409 of this title.

* * * *

(9) In the case of review of any action of the Administrator to which this subsection applies, the court may reverse any such action found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or

(D) without observance of procedure required by law, if (i) such failure to observe such procedure is arbitrary or capricious, (ii) the requirement of . . . [a timely objection] has been met, and (iii) [the errors were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made] . . . .

* * * *

42 U.S.C. § 7607.

These provisions of the Act assign this court a restricted role in reviewing air quality standards. *Lead Industries Ass'n, Inc. v. EPA*, *supra* at 30. The Administrator's construction of the Act will be upheld if it is reasonable, *id.* at 29-30, and though it is our duty to

undertake a "searching and careful" inquiry into the facts, our view of the evidence "is not designed to enable us to second-guess the agency's expert decision-maker." *Id.* at 26, 27. Reversal for procedural defaults under the Act will be rare because the court must first find that the Administrator was arbitrary or capricious, that he overruled a relevant and timely objection on the point in question, and that the errors were so significant that the challenged rule would likely have been different without the error. 42 U.S.C. § 7607(d)(9)(D); *Sierra Club v. Costle*, No. 79-1565 (D.C. Cir. April 29, 1981) slip op. at 182-83, 193-94.

IV.

Substantive Challanges To The Ozone Standards

Petitioner American Petroleum Institute contends that the primary ozone standard is not rational because, it alleges, no adverse health effects have been proven below 0.25 ppm with two hours exposure. (Br. for API at 31-44) API also argues that EPA must consider whether the 0.12 ppm standard is attainable and whether the anticipated costs of meeting that standard are justified when compared with the results to be achieved. *Id.* at 51-68. Petitioner Houston contends that the ozone standards are arbitrary and capricious because natural ozone levels and other physical phenomena in the Houston area prevent it from meeting the standards. (Br. for Houston at 4-22) Houston argues that the standards are also arbitrary and capricious because the control strategies promulgated by EPA will not reduce ozone levels. *Id.* at 22-26.

Petitioner Commonwealth of Virginia contends that EPA acted arbitrarily and capriciously in retaining the single hour averaging test for measuring compliance with the ozone standards. Virginia argues that the method chosen is not supported by logic or medical evidence, is costly, and will have no demonstrable bene-

ficial effect on air quality. (Br. for Virginia at 3-13) Petitioner Natural Resources Defense Council contends that the Administrator misinterpreted the Act in adopting standards for ozone alone and thus rescinding existing standards for other photochemical oxidants. (Br. for NRDC at 35-44) NRDC also argues that the Administrator failed to establish an adequate margin of safety in the primary ozone standard. *Id.* at 44-66.

API's argument that the Administrator erred in not considering attainability and cost justifications for the ozone standards was specifically rejected in the *Lead Industries* case, *supra* at 32. We stated there that under section 109 of the Act "the Administrator may not consider economic and technological feasibility in setting air quality standards . . . [because] of a deliberate decision by Congress to subordinate such concerns to the achievement of health goals." *Lead Industries, supra* at 33. In a lengthy analysis of the Act and its legislative history we concluded that the "technology-forcing" requirements of the Act were expressly designed to force regulated sources to develop pollution control devices that might at the time appear to be economically or technologically infeasible. *Lead Industries, supra* at 34-35.

API's other argument is that the standards are not supported by substantial evidence. We reject this argument because the record is replete with support for the final standards. The studies discussed in the criteria document constitute a rational basis for the finding that adverse health effects occur at ozone levels of 0.15 to 0.25 ppm for sensitive individuals. We need not find that each study discussed in the criteria document is accurate and reliable. The proper function of the court is not to weigh the evidence anew and make technical judgments; our role is limited to determining if the Administrator made a rational judgment. We find that the Administrator's conclusion that normal body functions are "disrupted" at low ozone levels, 44 Fed. Reg. 8213

(1979), is supported by the studies of De Lucia and Adams (effects at 0.15 to 0.30 ppm) (J.A. Ex. 1 at 9-18, Hazucha (effects as 0.25) (J.A. Ex. 1 at 1-15), Wayne (effects at 0.15) (J.A. Ex. 1 at 10-57), Herman (effects at 0.15 to 0.39) (J.A. Ex. 1 at 1-22-23), among others indicated in the record. The court finds no reason to hold that the Administrator abused his discretion in crediting the various studies relied on, even the acknowledged uncertainties in some of the conclusions. The Administrator noted that "a clear threshold of adverse health effects cannot be identified with certainty for ozone." 44 Fed. Reg. 8213 (1979). Because the Administrator acknowledged the uncertainty of his task and made a rational judgment, we cannot second-guess his conclusion. *Lead Industries, supra,* at 25-28; *See Motor & Equipment Manufacturers Ass'n v. EPA,* 201 U.S. App. D.C. 109, 119-20, 627 F.2d 1095, 1105-06 (1979), *cert. denied,* 446 U.S. 952 (1980); *Hercules, Inc. v. EPA,* 194 U.S. App.D.C. 172, 598 F.2d 91 (1978).

Houston's argument that because natural factors make attainment impossible the Administrator acted arbitrarily and capriciously in setting the primary ozone standard at an "unattainable" level is addressed in part by our analysis of API's attainability argument. Attainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards. *Lead Industries, supra* at 32-33. Further, the agency need not tailor national regulations to fit each region or locale. *NRDC v. EPA,* No. 79-1639 (D.C. Cir. May 7, 1981) slip op. at 34. We also note that compliance extensions are available in some cases, 42 U.S.C. § 7501(a)(2) (Supp. III 1979), and that Congress is aware that some regions are having difficulty in meeting the national standards. *See* 42 U.S.C. § 7501, *et seq.* (Supp. III 1979) (Part D of Title I, setting special requirements for states which have not met standards).

Houston also contends that EPA's strategies for deducing ozone concentrations rely on a faulty premise: that ozone is caused in part by high concentrations of

hydrocarbons in the air. In arguing this point Houston relies on a study which allegedly establishes that reduction of hydrocarbon levels will not reduce ozone levels.[3] The study in question was considered by EPA and rejected on several grounds which undercut the reliability of its conclusions. 44 Fed. Reg. 8235 (1979). Because control of ozone by reduction of hydrocarbon levels is an established methodology (J.A. Ex. 1 at 1-2, 1-3) and because Houston's record evidence in rebuttal is sparse, we cannot find that the Administrator is wrong on this issue.

Petitioner Commonwealth of Virginia challenges the method which EPA selected to measure compliance with the primary standard. The method chosen by EPA measures the highest average ozone level in any one hour to determine compliance. 44 Fed. Reg. 8217-18 (1979). Virginia argues that it would be better to use a daily average ozone level to measure exposure. We find that the Administrator's selection of the maximum hourly average method is reasonable because it is calculated to measure the maximum exposure, which has been found to be a relevant factor in determining the likely consequences of ozone exposure.

Petitioner National Resources Defense Counsel argues that the Administrator has abdicated responsibility for regulation of photochemical oxidants other than ozone by relabeling the regulations here at issue. In 1971 when the first air quality standards were promulgated, the title of the regulation was "National primary and secondary ambient air quality standards for photochemical oxidants". 36 Fed. Reg. 8187 (1971). The title was some-

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[3] Houston also appended to its brief as Exhibit A a recent study which it contends supports its position in this regard. That exhibit is not part of the record and cannot undercut the Administrator's conclusions on review. 42 U.S.C. § 7607(d)(7)(A) (Supp. III 1979); *see* American Petroleum Institute v. Costle, 197 U.S. App. D.C. 254, 609 F.2d 20 (1979).

what misleading because the 1971 standards applied only to ozone, which was the sole photochemical oxidant measured for compliance. 43 Fed. Reg. 26967 (1978). The new standards challenged in this case expressly apply only to ozone and do not attempt to establish permissible levels for other photochemical oxidants. 43 Fed. Reg. 26985 (1978).

Despite NRDC's characterization of the Administrator's action, it appears that EPA has not abandoned its statutory responsibility to regulate pollutants which "may reasonably be anticipated to endanger public health or welfare." 42 U.S.C. § 7408(a)(1)(A) (Supp. III 1979). Rather, the Administrator has chosen to regulate the photochemical oxidant (ozone) that, in his judgment presents a predictable danger. (J.A. Ex. 1 at 1-31) The setting of the ozone standard is not the only action taken by the agency with regard to photochemical oxidants; research concerning the less well known oxidants continues. 44 Fed. Reg. 8204 (1979). The Administrator's approach to photochemical oxidants is reasonable, given the uncertain information concerning the class as a whole.

NRDC also argues that the Administrator failed to establish an adequate margin of safety in the primary standard. As required by the statute, the Administrator promulgated air quality standards that are calculated to "protect individuals who are particularly sensitive to the effects of pollution." *Lead Industries, supra,* at 43. In setting margins of safety the Administrator need not regulate only the known dangers to health, but may "err" on the side of overprotection by setting a fully adequate margin of safety. *See Environmental Defense Fund v. EPA*, 194 U.S. App. D.C. 142, 161-62, 598 F.2d 62, 80-81 (1978). Of course the Administrator's conclusions must be supported by the record, and he may not engage in sheer guesswork. Where the Administrator bases his conclusions as to an adequate margin of safety on a reasoned analysis and evidence of risk, the

court will not reverse. NRDC argues that the Administrator erred in setting a primary standard that does not protect sensitive individuals against easily predicted risks. In so arguing NRDC essentially ignores the mixed results of the medical studies evident in the record, choosing instead to rely only on the studies that favor its position. The Administrator, however, was required to take into account all the relevant studies revealed in the record. Because he did so in a rational manner we will not overrule his judgment as to the margin of safety.

The Administrator concluded that the medical evidence "suggest[ed] the real possibility of significant human adverse health effects below 0.15 pp. Consequently . . . [he] determined that a standard of 0.12 ppm is necessary and is sufficiently prudent unless and until further studies demonstrate reason to doubt that it adequately protect public health". 44 Fed. Reg. 8217 (1979). Having determined that the "probable level for adverse effects in sensitive persons is in the range of 0.15-0.25 ppm", 44 Fed. Reg. 8216 (1979), the Administrator considered the evidence in the record that related to less predictable risks of ozone exposure, a relevant consideration in setting margins of safety. The Administrator considered the lack of medical evidence concerning especially sensitive persons, the possibility that ozone and other pollutants might combine to create cumulative effects, the significance of long-term exposure to otherwise safe ozone levels, inconclusive studies indicating very low ozone damage thresholds, and uncertainties arising from meterological and calibration errors in measurements. *Id.* The Administrator also indicated that the results of the risk assessment study, described at page 4, *supra*, did not support any safety margin above 0.12 ppm. 44 Fed. Reg. 8217 (1979). Given the nature of the task assigned to the Administrator, which is to make an informed judgment based on available evidence, we find that the Administrator's selection of a margin of safety is rational. *See Lead Industries, supra* at 62.

V.

PROCEDURAL CHALLENGES

Petitioners allege numerous procedural errors: EPA's relationship with the Science Advisory Board (SAB) and Advisory Panel on Health Effects of Photochemical Oxidants (Shy Panel), post-comment period contacts between EPA and the White House, exclusion of documents from the record, and last-minute additions to the record by EPA.

Under the procedural provisions of the Clean Air Act, 42 U.S.C. § 7607(d), we may invalidate the ozone standard because of procedural error only if (1) the agency's failure to observe procedural requirements was arbitrary and capricious, (2) an objection was raised during the comment period, or, where the grounds for such an objection arose after the comment period and the objection is of "central relevance to the outcome of the rule," the objection was raised on a petition for reconsideration before the agency, and (3) "the errors were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made." 42 U.S.C. § 7607(d)(7) & (8). As we noted in *Sierra Club v. Costle*, *supra* at 183, "[t]he essential message of so rigorous a standard is that Congress was concerned that EPA's rulemaking not be casually overturned for procedural reasons, and we of course must respect that judgment."

1. *Science Advisory Board (SAB)*

API and Houston contend that in promulgating the ozone standards EPA violated section 8(e) of ERDDAA, 42 U.S.C. § 4365(e) (Supp. III 1979) by failing to obtain approval of the criteria document from the SAB and to submit the proposed standards to the SAB for review. Section 8(e) provides, in relevant part, that

> (e) (1) The Administrator, at the time any proposed criteria document, standard, limitation, or regulation under the Clean Air Act . . . is provided to any other Federal agency for formal review and comment, shall *make available* to the [Science Advisory] Board such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information . . . .
>
> (2) The Board *may make available* to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed criteria document, standard, limitation, or regulation, together with any pertinent information in the Board's possession. (Emphasis supplied)

The language of the statute indicates that making a proposed criteria document and standard available to the SAB for comment is mandatory but that SAB approval is not required before proceeding to the final stage of rulemaking. This interpretation is supported by the Conference Report underlying this provision of the ERDDAA, which states in pertinent part that

> The Science Advisory Board is intended to be advisory only. The Administrator will still have the responsibility for making the decisions required of him by law. The reviews and comments of the Board are to be provided to the Administrator for his use. . . .

H.R. REP. NO. 95-722, 95th Cong., 1st Sess. 16 (1977). While "the intent of [the statutory] language is to insure that the Board is able to comment in a well-informed manner on any regulation that it so desires", "it should not be mandatory that they comment on all proposed regulations. . . ." *Id.* at 17 and 16. In short, the EPA was required under ERDDAA to submit the criteria document and standard to the SAB for comment, but it was not obligated

to obtain SAB approval of either before promulgation of a final standard.

The parties do not dispute that EPA submitted two drafts of the criteria document to the SAB and that substantial revisions were requested by the Board. The SAB agreed to cast ballots indicating approval or disapproval of the document based upon a third draft of only the "summary and conclusions" chapter of the document. After submission of the chapter, six of the eleven members of the SAB voted to approve the document subject to (1) stated reservations and (2) the assumption that the revised chapter accurately reflected corresponding changes in the entire document. (J.A. at 289-306) Two SAB members found the documents unacceptable, and the remaining three said that they were unable to make a judgment at that time. *Id.* The petitioners contend that the final criteria document, which was never submitted to the SAB, did not incorporate the changes requested by the Board, while EPA argues that the final criteria document adequately addressed the SAB's concerns.

The EPA action does not constitute a violation of section 8(e) of the ERDDAA. The Act requires only that the EPA submit the criteria document to the Board for advice and comment; it does not require that the Administrator obtain approval of the SAB or incorporate all suggested changes. While it might have been preferable for the EPA to have submitted the final criteria document to the SAB, we note that the SAB itself agreed to the course followed. (J.A. Ex. 2 at 563, 578) Given the extent of SAB comment on the criteria document, we cannot find that the document was not "made available" to the Board within the meaning of Section 8(e).

The proposed ozone standard, on the other hand, was never made available to the Board for advice and comment. Section 8(e) makes the submission of any proposed standard to the SAB mandatory. EPA contends that because the standard is based on the criteria document, submission

of the standard to the SAB would have been redundant. This argument is unpersuasive; the statute explicitly mandates that standards be submitted to the Board for review. Accordingly, the failure to submit the standards was a violation of procedure required by law. We cannot find, however, that this error was "so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed" had the proposed standards been submitted to the SAB. 42 U.S.C. § 7607(d)(8). The final standard of 0.12 ppm represents an allowance for a margin of safety in light of the adverse health effects range stated in the criteria document (0.15-0.25 ppm). Because any SAB review of the standard would have involved review of the criteria document, i.e., the scientific and technical basis for the standard, we cannot hold that the standard would likely have been significantly changed had it been submitted to the Board. The Administrator's final standard, as noted *supra* at 8, is rational and supported by the record. Although the failure to submit the proposed standards to the SAB was a violation of section 8(e) of the ERDDAA, the circumstances indicate that the error was not so central as to constitute grounds for invalidating the final standards.

2. *Shy Health Effects Panel and Risk Assessment Study*

API and Houston also argue that the EPA Advisory Panel on Health Effects of Photochemical Oxidants (Shy Panel) was an advisory committee within the meaning of the Federal Advisory Committee Act (FACA). 5 U.S.C. app. I, § 1 *et seq.* (Supp. I 1977). Petitioners assert that because EPA failed to observe several requirements of FACA, the actions of the Shy Panel and the EPA reliance on the panel's risk assessment study require invalidation of the standard.

In early 1977 EPA officials responsible for developing the ozone standard asked Dr. Carl Shy of the Institute for

Environmental Studies, University of North Carolina at Chapel Hill, to head a panel of paid environmental experts which would prepare "a detailed report on the translation of health data into an ambient air quality standard for photochemical oxidants." (Br. of API at 20) Dr. Shy was a leading advocate of the existing 0.08 ppm ozone standard. *Id.* The panel met privately on June 7 and 8, 1977. A first draft of the panel report, co-authored by Shy and an EPA official, strongly endorsed the existing 0.08 standard. Following some minor revisions, the final draft of the Shy Panel report was submitted to the EPA in late 1977, made available for public comment in December 1977, and placed in the rulemaking docket on March 22, 1978. (Br. of EPA at 126) The report, which used a "risk assessment" technique to conclude that 0.08 ppm was the proper ozone standard, was made part of the criteria document and cited as one of the bases for the final 0.12 ppm standard. (Br. of API at 29)

The FACA defines an advisory committee, in relevant part as "any . . . panel . . . which is . . . established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for . . . one or more agencies . . . ." 5 U.S.C. app § 3(2)(C). Petitioners contend that because the Shy Panel clearly is an advisory committee within the meaning of this provision, the conduct of the panel violates several provisions of FACA and that EPA reliance on the panel's study as a basis for the final rule requires invalidation of the standard. For example, it is argued that the choice of a known partisan to chair the panel violates the FACA requirements that the committee be "fairly balanced" and that it not be "inappropriately influenced" by any "special interest." 5 U.S.C. app. § 5(b)(2)-(3). It is also asserted that the private meetings of the panel violate the FACA requirement that public notice and opporunity for public participation be given. 5 U.S.C. app. §§ 10(a)(2) and (d)(3). EPA asserts, on the other hand, that the Shy Panel is not subject to FACA because the group con-

sisted of paid consultants and the legislative history of FACA indicates that the Act was not intended to apply to persons having contractual relationships with the government. CONF. REP. NO. 92-1403, 92d CONG., 2d SESS. (1972). *See Lombardo v. Handler*, 397 F. Supp. 792 (D.D.C. 1975), *aff'd mem.*, 178 U.S. App.D.C 277, 546 F.2d 1043 (1976), *cert. denied*, 431 U.S. 932 (1977). In any event, argues EPA, none of the Shy Panel actions violated FACA.

We need not reach the questions whether the Shy Panel was an advisory committee within the meaning of FACA and whether violations of FACA occurred. Even were we to find that the panel was subject to FACA, that violations of the Act occurred, and that reliance on the risk assessment study was therefore illegal, we would not be able to say that there is a substantial likelihood that the 0.12 ppm standard would have been significantly different if such errors had not been made. The ultimate adoption of a 0.12 ppm standard constitutes a rejection of the Shy Panel's conclusion that the ozone standard should not be relaxed. Moreover, even though the Shy Report was cited as one of the bases for the final standards, the criteria document otherwise fully supports the 0.12 ppm standard as a figure representing a margin of safety below the 0.15-0.25 ppm danger zone. In short, absent the Shy Panel report, there is a substantial likelihood that the standard would have been the same. We therefore cannot invalidate the standard based on the alleged procedural irregularities.

3. *EPA Exclusion of API Submission Regarding Natural Hydrocarbons*

API asserts that the EPA erred in failing to consider and by excluding from the docket and record an API post-comment period submission concerning natural organic emissions from vegetation.

Section 307(d)(4)(B) of the Clean Air Act, 42 U.S.C. § 7607(d)(4)(B) requires the Administrator to place in the docket all documents, even those not submitted during the comment period, determined to be "centrally relevant" to the rulemaking. API, in submitting the above documents, noted in its request that they related to the issue of whether "attainment of the proposed standards would be precluded in most areas of the nation by natural background levels of ozone resulting in part from natural hydrocarbon emissions." (J.A. at 1003) EPA refused to docket most of the documents submitted by API on the ground that the question of attainability is not relevant to the setting of ambient air quality standards under the Clean Air Act. As noted, *supra* at 10, the EPA position that attainability is not central to a rulemaking of this type is correct. Accordingly, EPA's decision to exclude the API submission was proper.

4. *EPA's Last-Minute Addition to the Record*

Finally, NRDC contends that EPA violated the administrative procedure requirements of the Clean Air Act by placing in the record, after the close of the comment period and one day before promulgation of the final rule, an EPA staff paper entitled "Evaluation of Alternative Secondary Ozone Air Quality Standards". The statement accompanying the final rule indicated that this study was the primary basis for the change from an 0.08 ppm to 0.12 ppm secondary standard. 44 Fed. Reg. 8217 (1979). NRDC argues that the failure to give notice or opportunity to comment on any analysis so central to the final decision warrants invalidation of the secondary standard.

The last-minute addition to the record of a study which constituted the basis for the final secondary standard is disturbing. The study was never exposed to public scrutiny or comment. However, the procedural requirements of the Clean Air Act do not permit NRDC to raise this objection for the first time on appeal. *See Oljato Chapter of the Navajo Tribe v. Train*, 169 U.S. App. D.C. 195,

207-08, 515 F.2d 654, 666-67 (D.C. Cir. 1975). Section 307(d)(7)(B) of the Act, 42 U.S.C. § 7607(d)(7)(B) provides that:

> (B) Only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. If the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the ground for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed. If the Administrator refuses to convene such a proceeding, such person may seek review of such refusal in the United States court of appeals for the appropriate circuit (as provided in subsection (b) of this section). Such reconsideration shall not postpone the effectiveness of the rule. The effectiveness of the rule may be stayed during such reconsideration, however, by the Administrator or the court for a period not to exceed three months.

The statute states that before this court may review a procedural objection the parties must raise the objection on petition for reconsideration before the EPA when the grounds for such objection "arose after the period for public comment (but within the time specified for judicial review". This reading is confirmed by the legislative history of this provision, which states in pertinent part:

> Section 307(d)(7)(B) would specify the circumstances in which a reviewing court may consider data and arguments that were not presented to the

> agency during the rulemaking. Even in such cases, however, the Agency must first be given an opportunity to pass on the significance of the materials and determine whether supplementary proceeding [sic] are called for or not. Thus, the committee bill confirms the court's decision in *Oljato Chapter of the Navajo Tribe v. Train*, 515 F.2d 654 (D.C. Cir. 1975).

H.R. REP. 95-294, 95th CONG., 1st SESS, 323 (1977). *See generally, Sierra Club v. Costle, supra* at 193-94.

The record before us does not suggest that any party, including NRDC, filed petitions for reconsideration with the EPA. The grounds for NRDC's objection were clear as of the date of promulgation of the final rule. Had NRDC complied with the statutory requirement of filing a petition for reconsideration, it could have commented on the staff study and the EPA could have responded during the period when the petition was pending. Because the required petition for reconsideration was never filed, we cannot reach the merits of the NRDC objection. *See generally, Sierra Club v. Costle, supra* at 200-201 & n.497.

Although we refer to a "petition for reconsideration" in this opinion, it should be noted that any formal communication to the Administrator that specifically states an objection, requests reconsideration of Agency action because of the objection, and provides notice to interested parties, would satisfy the statutory requirement for an "objection . . . raised with reasonable specificity." 42 U.S.C § 7607(d)(7)(B). The record reflects no such formal communication from NRDC.

5. *Post-Comment Period White House Contacts*

NRDC contends that a series of post-comment period oral contacts between officials of the EPA and the White House and its agencies were not documented in the docket

or the record. NRDC argues that this constitutes a violation of Clean Air Act Section 307(d)(4)(B)(ii), 42 U.S.C. § 7607(d)(4)(B)(ii) (1976), which provides that:

> (ii) The drafts of proposed rules submitted by the Administrator to the Office of Management and Budget for any interagency review process prior to proposal of any such rule, all documents accompanying such drafts, and all written comments thereon by other agencies and all written responses to such written comments by the Administrator shall be placed in the docket no later than the date of proposal of the rule. The drafts of the final rule submitted for such review process prior to promulgation and all such written comments thereon, all documents accompanying such drafts, and written responses thereto shall be placed in the docket no later than the date of promulgation.

As we have said, a petitioner must raise a procedural objection with the EPA if this court is to consider the objection. 42 U.S.C. § 7607(d)(7)(B). This rule applies even when the grounds for the objection first became known to the petitioner after the comment period ended, but before the period for petitioning for review expired. This is evident from the statute: ". . . if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed." 42 U.S.C. § 7607(d)(7)(B).

According to NRDC, it was alerted to the White House contacts as early as February 26 and 27, 1979, when hearings on executive branch review of environmental regulations were held by the Senate Subcommittee on Environmental Pollution. (NRDC Br. at 19, n.46, 28,

n.53) The Subcommittee examined the role of White House economic advisers. The final regulations were published in the Federal Register on February 8, 1979. 44 Fed. Reg. 8202. Thereafter NRDC had sixty days to file its petition for review. 42 U.S.C. § 7607(b)(1). In that period NRDC could have petitioned the EPA for reconsideration based on its objection to the White House contracts. Because NRDC failed to exhaust the administrative remedy specifically required by the Act we may not and do not consider this objection to the Administrator's action. 42 U.S.C. § 7607(d)(7)(B); § 7607(d)(9)(D)(ii).

VI.

Conclusion

In summary, we hold that the primary and secondary standards for ozone emission are supported by a rational basis in the record. Although the EPA procedures were not a model of regulatory action, we hold that none of the alleged procedural errors warrants invalidation of the final standards.

Affirmed.

WALD, *Circuit Judge*, dissenting in part: I concur in all respects with Judge Robb's majority opinion, save one: I am troubled by the manner in which the court refuses to decide the *ex parte* issue for failure to raise it properly under section 307.

The majority opinion disposes of NRDC's challenge concerning post-comment period White House contacts by holding that NRDC failed to raise this objection before EPA in a timely manner, and is therefore precluded from doing so here under 42 U.S.C. § 7607(d)(9)(D); § 7607(d)(7)(B). EPA itself, however, nowhere claims such a bar to deciding this issue on the merits, and I find the present record inconclusive on whether this issue was appropriately brought to EPA's attention. I would therefore have posed a single interrogatory to the parties to ascertain whether a timely objection by NRDC was in fact made on this issue so as to bring it within the scope of our review under this statute.

As the majority recognizes, the relevant section, 42 U.S.C. § 7607(d)(7)(B), requires only an "objection [of central relevance] . . . raised with reasonable specificity" to require the Administrator to convene a proceeding for reconsideration.

While we may be confident here that any *formal* petitions for reconsideration would appear in the record, we cannot be as sure about the presence of other, less formal objections to the rulemaking. The latter would *not* necessarily appear in the record on appeal, because the record for judicial review as defined in section 307(d)(7)(A) does not include all post-promulgation objections. It is also possible that an objection made to the alleged *ex parte* contacts even before promulgation might not have been placed in the record as being "centrally relevant."

Without more reliable knowledge that no reasonably specific, timely objection was made by NRDC regarding post-comment period communications, I would not find the

issue barred in this court without some statement by the parties addressing this point. My suspicion that an appropriate objection may in fact have been made is fueled by (1) Environmental Defense Fund testimony in the February, 1979 hearings before the Senate Subcommittee on Environmental Pollution,[1] that it had written Administrator Costle two weeks before about White House-EPA *ex parte* contacts; and (2) EPA's own failure to object to NRDC's claims on the ground that the claims were not properly raised before the agency. EPA, in fact, defends exclusively on the merits, asserting that the post-comment period White House communications were proper and duly recorded. *See* Brief for Respondent EPA at 101-10.

In short, I do not think it reasonable to assume, on the record before us and in the absence of any such assertion by EPA, that no timely objection was made on the *ex parte* issue. I would instead have resolved this factual ambiguity in the record before deciding whether to pass on the merits of the *ex parte* issue.

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[1] *See* Executive Branch Review of Environmental Regulations: Hearings Before the Subcomm. on Environmental Pollution of the Senate Comm. on Environment and Public Works, 96th Cong., 1st Sess. 57 (Feb. 26, 1979) (testimony of Robert Rauch, Staff Attorney, Envt'l Def. Fund).